IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Imtiaz Chaudry

Title:

Inhalable Formulations For Treating Pulmonary

Hypertension and Methods of Using Same

Appl. No.:

TBA

Filing Date:

TBA

Examiner:

TBA

Art Unit:

TBA

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

Sir:

Submitted herewith on modified Form PTO-1449 is a listing of documents known to the undersigned in order to comply with applicant's duty of disclosure pursuant to 37 CFR 1.56. Copies of each listed document are enclosed herein.

The submission of any document herewith is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive an rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a <u>prima facie</u> prior art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The instant Information Disclosure Statement is being filed before the mailing date of any action on the merits. Accordingly, pursuant to 37 CFR §1.97, no certification, petition and fee are required.

Applicants respectfully request that the listed documents be considered by the Examiner and be made of record in the present application and that an initialed copy of form PTO-1449 be returned in accordance with MPEP §609.

Respectfully submitted,

Date: 6/36/63

By:

Thomas J. Parker Reg. No.: 42,042

Coudert Brothers LLP

1114 Avenue of the Americas

New York, NY 10036

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	6,559,313	05/06/2003	Myers, et al.	546	279.1	03/22/2002					
	6,174,906	01/16/2001	Elliot, et al.	514	365	10/01/1999					
	6,197,762	03/06/2001	Garvey, et al.	514	174	09/18/1998					
	5,968,911	10/19/1999	Lawson, et al.	514	46	02/18/1997					
	5,873,359	02/23/1999	Zapol, et al.	128	203.12	12/09/1994					
	20020115655	08/22/2002	Mehanna, Ahmed S.	514	217.03	10/31/2001					
	20010031738	10/18/2001	Schwarz, Margaret A.	514	44	12/15/2000					
	20030078190	04/24/2003	Weinberg, Marc S.	514	1	05/24/2002					
	20020132787	09/19/2002	Eljamal, Mohammed, et al.	514	44	09/19/2002					
	FOREIGN PATENT DOCUMENTS										

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Canadian Journal of Anesthesia, Volume 49, Number 9, November 2002, Excellence in clinically-related research and knowledge, Cardiothoracic Anesthesia, Respiration and Airway, Inhaled iloprost controls pulmonary hypertension after cardiopulmonary bypass, Kassiani Theodoraki MD DEAA, Panagiota Rellia MD, Apostolos Thanopoulos MD, Loukas Tsourelis MD, Dimitrios Zarkalis MD, Petros Sfyrakis MD, Theophani Antoniou MD

The England Journal of Medicine, Volume 327, July 9, 1992, Number 2, The Effect of High Doses of Calcium-Channel Blockers on Survival in Primary Pulmonary Hypertension, Stuart Rich, MD, Elizabeth Kaufman, RN, and Paul S. Levy, Sc.D

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FOREIGN PATENT DOCUMENTS TRANSLATION DOCUMENT NUMBER DATE COUNTRY CLASS SUBCLASS YES NO OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) What Atenolol Is and What it Does, http://www.sunderland.ac.u.k/-hs0dad/profile/atenolol/what.htm The Columbia Encyclopedia, Sixth Edition 2001, ACE inhibitor, http://www.bartleby.com/65/ac/ACE-i.html **EXAMINER DATE CONSIDERED** *EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not

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Enalaprilat Injection, http://www.bedordlabs.com/products/010-10.html

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